



DEPARTMENT OF HEALTH & HUMAN SERVICES

9-213d
Public Health Service
Food and Drug Administration

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

February 24, 2005

Via Federal Express

Mark L. McAfee, CEO
Organic Pastures Dairy Company
7221 S. Jameson Ave.
Fresno, CA 93706

WARNING LETTER

Dear Mr. McAfee:

Our inspection of your firm located at 7221 S. Jameson Ave., Fresno, California, on April 5-9, 2004, and samples of your products obtained through November 2004, documented violations of the Public Health Service Act (PHS Act) and a Federal regulation promulgated under the PHS Act.

Our inspection and subsequent investigation determined that you distribute unpasteurized milk, buttermilk, butter, cream, and colostrums in interstate commerce, in finished form for human consumption. Such distribution is a violation of the PHS Act, Title 42, United States Code, Sections 264(a) and 271(a), and the implementing regulation codified in Title 21, Code of Federal Regulations (C.F.R.), section 1240.61(a). The regulation bans the delivery, sale, or distribution in interstate commerce of milk and milk products in final package form for human consumption unless they have been pasteurized. Your products are "milk" and "milk products" as defined by 21 C.F.R. § 1240.3. Further, your milk and milk products, shipped directly to consumers for consumption without subsequent processing and pasteurization, are in final package form for human consumption. Though your products are shipped in a [REDACTED] state, your products are still considered to be in final package form for human consumption. For your information, we have enclosed a copy of the regulation as it was published in the Federal Register, 52 FR 29509 (Aug. 10, 1987).

The above is not intended to be an all inclusive list of violations. It is your responsibility to ensure adherence with all requirements of the PHS Act and implementing regulations. You should take prompt action to correct this deviation and prevent any future recurrence. Failure to make prompt corrections could result in regulatory action without further notice. Possible actions include seizure, injunction and/or prosecution.

Please notify this office within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent recurrence of similar violations. If corrective actions

cannot be completed within 15 days, state the reason for the delay and the time within which the corrections will be completed.

Please address your response and any questions to the Food and Drug Administration, San Francisco District, 1431 Harbor Bay Parkway, Alameda, CA 94502, attention: Russell A. Campbell, Compliance Officer.

Should you require any assistance in understanding the contents of this letter, do not hesitate to contact Mr. Campbell at the above address or at 510-337-6861.

Sincerely yours,

Madeline V. Asmundson

for:

Barbara J. Cassens
District Director